UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS Alexandria, Virginia 22313-1450 www.uspio.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,916	07/20/2005	Patrick Colin Hickey	RGC-LUX-P1	9549
44702 7590 01/13/2009 OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE			EXAMINER	
			LEE, SHUN K	
FLOOR 17 NEW YORK.	FLOOR 17 NEW YORK, NY 10022-6894			PAPER NUMBER
,			2884	
			MAIL DATE	DELIVERY MODE
			01/13/2000	DADED

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/542.916 HICKEY, PATRICK COLIN Office Action Summary Examiner Art Unit Shun Lee 2884 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 December 2008 and 16 December 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-3.5-7.11-14.18.19.21 and 22 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-3.5-7.11-14.18.19.21 and 22 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) ____ are subject to restriction and/or election requirement. Application Papers The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 20 July 2005 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date __ 6) Other:

Page 2

Application/Control Number: 10/542,916

Art Unit: 2884

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on
2 December 2008 has been entered.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1, 3, 18, 19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Nast (US 4,575,143) and Valenta (US 5,321,261).

In regard to claims 1 and 21, it should be noted that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" (*Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)) if the prior art apparatus teaches all the structural limitations of the claim (MPEP § 2114). Thus, "the light output intensity of the device is pre-determinable by calculating the half-life correction of the GTLS" were not given any patentable weight since the

Application/Control Number: 10/542,916
Art Unit: 2884

light measuring apparatus does not appear to impose any additional structural limitations on the claimed luminescent device. Kessler et al. disclose (Figs. 1 and 2) a removable luminescent device comprising a gaseous tritium light source (GTLS 100) within a housing (101), the housing (101) being within an outer casing (9b), the luminescent device providing a light output of pre-determinable intensity (see EPO automated translation of abstract). The luminescent device of Kessler et al. lacks that the outer casing is magnetic and is sized and shaped to fit in an individual well of a standard size well plate. However, Nast teaches (column 1, lines 51-52) to provide a magnetic handling tool in order to retrieve small objects having a magnetic component from locations that cannot be reached by a mechanical tool. Further, Valenta teaches a luminometer used to measure bioluminescent emissions (column 1, lines 18-19) simultaneously from different wells (column 2, line 67 to column 3, line 2), wherein each of a plurality of radioluminescent standards are sized using inserts (42 in Fig. 4) that fit into individual well (e.g., S6, S18, S30, S42 in Fig. 2; column 4, lines 24-26) of a 96 well plate containing a matrix of sample wells S1-S96 (column 2, lines 58-62) for calibrating the photomultipliers (e.g., P1-6 and P7-12; column 2, lines 58-62) that can be used for simultaneous measurements from different wells. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a magnetic insert as the outer casing for a desired size of a removable luminescent device of Kessler et al., in order to retrieve the removable luminescent device that has been fitted into an individual well of a standard size well plate that cannot be easily reached by hand.

Application/Control Number: 10/542,916 Page 4

Art Unit: 2884

In regard to claim 3 which is dependent on claim 1, Kessler et al. also disclose (Fig. 2) an outer casing (9b) that inherently has at least one optically transparent or translucent portion to allow for the transmission of light from the GTLS (100).

In regard to claim 22, the cited prior art is applied as in claim 1 above. Kessler et al. also disclose (see EPO automated translation of abstract and column 3, line 35 to column 4, line 25) a method for calibrating a light measuring apparatus comprising the steps of; obtaining a reading of light output from a luminescent device comprising a gaseous tritium light source (GTLS); and adjusting a reading of light output of the light measuring apparatus to a pre-determined intensity of the luminescent device, the pre-determined light output being determined by calculating the light power as a function of time (i.e., the half-life correction of the GTLS). Kessler et al. lacks that the luminescent device is removably fitted into and left in a standard size well plate during use so that the calibration of the light measuring apparatus may be tested whilst measuring the light output of an analyte sample. However, Valenta teaches a luminometer used to measure bioluminescent emissions (column 1, lines 18-19) simultaneously from different wells (column 2, line 67 to column 3, line 2), wherein each of a plurality of radioluminescent standards are sized using inserts (42 in Fig. 4) that fit into individual well (e.g., S6, S18, S30, S42 in Fig. 2; column 4, lines 24-26) of a 96 well plate containing a matrix of sample wells S1-S96 (column 2, lines 58-62) for calibrating the photomultipliers (e.g., P1-6 and P7-12; column 2, lines 58-62) that can be used for simultaneous measurements from different wells. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to dispose the

Art Unit: 2884

removable luminescent device of Kessler *et al.* within an insert sized to fit in an individual well of a standard size well plate (*e.g.*, a 6 well plate containing samples in the other individual wells) housed in a sample holder of a luminometer, in order to measure absolute luminescence from the samples.

In regard to claims **18** and **19**, the cited prior art is applied as in claim 22 above.

Kessler *et al.* disclose (see EPO automated translation of abstract and column 3, line 35 to column 4, line 25) a method of analyzing a sample, said method comprising:

- (a) determining a pre-determinable light output intensity of a luminescent device comprising a gaseous tritium light source (GTLS) by calculating the light power as a function of time (i.e., the half-life correction of the GTLS);
- (b) measuring the intensity of light emitted by a luminescent device;
- (c) adjusting a reading of light output of a light measuring apparatus to the predetermined light output intensity of the luminescent device; and
- (d) obtaining a reading of light output from an analyte sample.

The method of Kessler et al. lacks that the luminescent device fitted and left in an individual well (of a standard size well plate placed in a sample holder of the light measuring apparatus) during use so that the calibration of the light measuring apparatus may be tested whilst measuring the light output from the analyte sample comprising molecules or living cells placed in another well of the standard size well plate. However, Valenta teaches a luminometer used to measure bioluminescent emissions (column 1, lines 18-19) simultaneously from different wells (column 2, line 67 to column 3, line 2), wherein each of a plurality of radioluminescent standards are sized

Application/Control Number: 10/542,916
Art Unit: 2884

using inserts (42 in Fig. 4) that fit into individual well (e.g., S6, S18, S30, S42 in Fig. 2; column 4, lines 24-26) of a 96 well plate containing a matrix of sample wells S1-S96 (column 2, lines 58-62) for calibrating the photomultipliers (e.g., P1-6 and P7-12; column 2, lines 58-62) that can be used for simultaneous measurements from different wells. Further, bioluminescence is defined ¹ as "the emission of light from living organisms; also: the light so produced". Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to dispose the luminescent devices of Kessler *et al.* within an insert sized to fit in individual wells (e.g., S6, S18, S30, S42) and to dispose samples of living cells into other individual wells (e.g., S8, S20, S32, S44) of a 96 well plate in order to measure absolute bioluminescence from living cells.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Kessler et al. in view of Nast and Valenta as applied to claim 1 above, and further in view of MacHutchin et al. (US 2,953,684).

In regard to claim **2** which is dependent on claim 1, the modified device of Kessler *et al.* lacks an explicit description that the GTLS comprises 10 to 20 mCi of tritium. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, lines 3-11) that in one embodiment the GTLS have a radiant flux of approximately 15 µlm to 3.5 mlm and that the radiant flux can be adjusted by the tritium gas pressure for a given luminescent device configuration. Since Kessler *et al.* do not disclose and/or require a specific tritium gas pressure, one having ordinary skill in the art at the time of the invention would reasonably interpret the unspecified tritium gas pressure of

¹ Merriam Webster's Collegiate Dictionary 10th Edition

Art Unit: 2884

Kessler *et al.* as a result effective variable that is to be adjusted so as to obtain a desired radiant flux. Further, MacHutchin *et al.* teach (column 3, line 65 to column 4, line 36) that for a given luminescent device configuration, the number of curies of gas depends on the gas pressure. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the tritium gas pressure (*e.g.*, 10 to 20 mCi of tritium gas) in the modified device of Kessler *et al.*, in order to obtain a desired radiant flux from the luminescent device.

 Claims 5, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of Nast and Valenta as applied to claims 1 and 3 above, and further in view of Adams et al. (US 6,549,279).

In regard to claim **5** which is dependent on claim 3, the modified device of Kessler *et al.* lacks an explicit description that the transparent or translucent portion comprises a neutral density filter. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a neutral density filter as the transparent or translucent portion in the modified device of Kessler *et al.*, in order to obtain a second calibration radiant flux from the same luminescent device.

Art Unit: 2884

In regard to claim **7** which is dependent on claim 1, the claim limitation "colouring means" is being treated under 35 U.S.C. 112, sixth paragraph and has been construed to cover the corresponding structure described in the specification (*e.g.*, "Coloured filters" in lines 29-31 on pg. 14) and equivalents thereof (MPEP § 2181). The modified device of Kessler *et al.* lacks an explicit description that the device further comprises coloring means to alter the color of the light output of the GTLS. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes for several pre-selected wavelengths. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a filter in the modified device of Kessler *et al.*, in order to obtain light having a desired wavelength.

In regard to claim 12 which is dependent on claim 1, the modified device of Kessler et al. lacks an explicit description that said device comprises a filter array. However, Kessler et al. also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams et al. teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. Therefore it would have been obvious to one having ordinary skill in the

Page 9

Application/Control Number: 10/542,916

Art Unit: 2884

art at the time of the invention to provide a filter array for the modified device of Kessler et al., in order to obtain a plurality of different calibration radiant fluxes from the same luminescent device.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Kessler et al. in view of Nast and Valenta as applied to claim 3 above, and further in view of Adams et al. (US 6,549,279) and Terashita et al. (US 5,073,008).

In regard to claim **6** which is dependent on claim 3, the modified device of Kessler *et al.* lacks an explicit description that the transparent or translucent portion is formed from glass or plastic. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. In addition, Terashita *et al.* teach (column 6, lines 65-68) that a neutral density filter comprises a glass plate or a plastic plate. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a neutral density filter formed from glass or plastic as the transparent or translucent portion in the modified device of Kessler *et al.*, in order to obtain a second calibration radiant flux from the same luminescent device.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Kessler et al. in view of Nast and Valenta as applied to claim 1 above, and further in view of Gelman et al. (US 5.389.774).

Art Unit: 2884

In regard to claim 11 which is dependent on claim 1, the modified device of Kessler et al. lacks that said device comprises a scalebar graticule. However, Gelman et al. teach (Fig. 4) to provide a calibration device comprising a light source (16) and scalebar graticule (15), in order to calibrate an optical measuring system. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a scalebar graticule in the modified device of Kessler et al., in order to calibrate an optical measuring system.

 Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of Nast and Valenta as applied to claim 1 above, and further in view of Leveille (US 2002/0096667).

In regard to claim 13 which is dependent on claim 1, Kessler et al. lacks a kit further comprising an additional one or more luminescent devices, wherein each of said devices providing a light output of a distinct intensity to the other devices of said kit.

However, Leveille teaches (paragraphs 1-9) to provide a calibration light kit, in order to calibrate a light measuring apparatus. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a plurality of the luminescent devices of Kessler et al. having different intensities as a calibration kit.

In regard to claim 14 which is dependent on claim 13, the kit of Kessler et al. lacks a magnetic handling tool. Nast teaches (column 1, lines 51-52) to provide a magnetic handling tool in order to retrieve small objects having a magnetic component from locations that cannot be reached by a mechanical tool. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide

Art Unit: 2884

a magnetic handling tool for the kit of Kessler et al., in order to retrieve the luminescent devices from locations that cannot be reached by hand.

Response to Arguments

 Applicant's arguments filed 2 December 2008 have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims 1-3, 5-7, 11-14, and 21 have been considered but are moot in view of the new ground(s) of rejection.

In regard to claims 18, 19, and 22, applicant argues that Kessler *et al.* do not disclose a device that is adjusted to the contours of a receptacle. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant also argues that Kessler et al. do not disclose or suggest that the intensity of the luminescent device is pre-determined by calculating the half-life correction. Examiner respectfully disagrees. Kessler et al. disclose (abstract) calculating the light power as a <u>function of time</u>. Therefore, Kessler et al. teach or suggest that the intensity of the luminescent device is pre-determined by calculating the half-life correction.

Applicant further argues that the invention is novel over Valenta. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

Art Unit: 2884

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant additionally argues that the disclosure of Kessler et al. teaches away from using a light standard at the same time as reading test samples, because it explicitly states that the test is to be carried out prior to testing of samples. Examiner respectfully disagrees. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments (MPEP § 2123).

In response to applicant's argument that sample measurement occurs after calibration in the example of Kessler *et al.* and that no absolute measurement is taken by Valenta, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (571) 272-2439. The examiner can normally be reached on Monday-Thursday.

Application/Control Number: 10/542,916 Page 13

Art Unit: 2884

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L./ Examiner, Art Unit 2884

/Constantine Hannaher/ Primary Examiner, Art Unit 2884